

Cook Group Incorporated

August 23, 1999

Dockets Management Branch (HFA-305) Food and Drug Administration 5630 Fishers Lane Room 1061 Rockville, Maryland 20852

Re: Docket No. 99N-1737

Dear Sir or Madam:

The Cook Group ("Cook") submits this comment in response to the Food and Drug Administration's ("FDA") June 22, 1999 *Federal Register* publication regarding public availability of information on clinical trials.

Cook is a holding company of an international corporation engaged in the manufacture of diagnostic and interventional products for radiology, cardiology, urology, gastroenterology, emergency medicine and surgery services. Cook has pioneered numerous products to improve patient treatment and care, including devices used in the Seldinger technique of angiography and in techniques for interventional radiology and cardiology. Many Cook products benefit patients by providing doctors with the means of diagnosis and therapeutic intervention without necessitating open surgical procedures. Cook sells over 15,000 different products which can be purchased in 130,000 different combinations.

Section 113 of FDAMA directed that the National Institutes of Health (NIH) establish, maintain and operate a data bank of information on clinical trials for serious and life-threatening diseases and conditions. It also instructed the Secretary of Health and Human Services (HHS), the Director of NIH and the Commissioner of the Food and Drug Administration (FDA) to collaborate and determine the feasibility of including device investigations within the scope of the data bank.

We are not familiar with what has been learned in assembling the data bank for drugs. However, it is Cook's view that HHS should utilize the experience gained in setting up that data bank to determine whether and how to move forward in the case of devices. If indeed it is found that there has been significant patient benefit by establishing this data bank for drugs, we believe it should be explored for medical devices.

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In analyzing this issue as it pertains to medical devices, it is important that HHS recognize the device industry is quite distinct from the pharmaceutical industry. Devices are manufactured by thousands of companies, most of which are very small. These small companies are responsible for much of the innovation in the industry. Many of them are privately held and were created to develop one particular product. Further, while most of the larger, publicly held device companies publicly disclose clinical trials as a matter of practice, the smaller, privately held companies generally do not. Confidentiality is particularly important for them. If potential competitors are aware of the developmental activities of a one product company and beat it to the market place, that will usually destroy the small enterprise.

Nonetheless, if it is demonstrated that disclosure of clinical trials for a device will significantly help patients who are very ill, it should be made. We recommend that any such disclosure in the device area be limited strictly to products used in treating serious or life-threatening diseases and conditions. The appropriate clinical trials for disclosure should be determined according to whether the Agency would engage in an expedited review of the product. The products that receive an expedited review are the types of products to which Congress felt patients need access. Patients who are not seriously ill or who have effective alternative therapies available to them are not interested in finding clinical trials.

It is also recognized that in some situations companies may want to have information on a clinical trial listed in the data bank, and should be permitted to add it if they elect. The data bank may assist in obtaining patients for some conditions with small populations.

We appreciate the opportunity to offer these comments. We believe that confidentiality of information regarding product development is important for innovation in our industry. However, if the experience with the drug data bank indicates that there is significant benefit to patients, disclosure of clinical trials for devices in limited types of cases is appropriate, in our judgment, and good public policy.

Respectfully,

Stephen L. Ferguson / Clar

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